

**Rec'd PCT/PTO 21 JUL 2005**

**PATENT**  
Docket No. 506612000103

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Dated: July 21, 2005 Signature: \_\_\_\_\_ (LILIA OLSEN)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Jay WOHLGEMUTH et al.

Serial No.: 10/512,028

Filing Date: April 24, 2003 (PCT/US03/13015)

For:

METHODS AND COMPOSITIONS FOR  
DIAGNOSING AND MONITORING  
AUTO IMMUNE AND CHRONIC  
INFLAMMATORY DISEASES

Examiner: Not Yet Assigned

Group Art Unit: Not Yet Assigned

**INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98**

**MS BOX PCT/DO/EO/US**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of the documents were previously submitted in an Information Disclosure Statement and/or Office Action, directed to the related application Serial Number 10/131,827 filed April 24, 2002, and, accordingly, copies are not included herewith. This protocol conforms with 37 C.F.R. § 1.98(d) and M.P.E.P. 609(A)(2). The Examiner is requested to make these documents of record in the application.

This Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☒ **Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.**
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
  - ☐ A fee is required. A check in the amount of \_\_\_ is enclosed.
  - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of \_\_\_ is enclosed.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing 506612000103. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: July 21, 2005

Respectfully submitted,

By Michael R. Ward

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/512,028
				Filing Date	April 24, 2003
				First Named Inventor	Jay WOHLGEMUTH
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	1	of	16	Attorney Docket Number	506612000103

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
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Sheet	3	of	16	Attorney Docket Number	506612000103

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
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Sheet	4	of	16	Attorney Docket Number	506612000103

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Sheet	5	of	16	Attorney Docket Number	506612000103

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Examiner Signature		Date Considered	
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Sheet	6	of	16	Attorney Docket Number	506612000103

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Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)					
	153.	EP	0 217 102 A2	4/8/1987			
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\*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
	198.	International Search Report mailed on September 30, 2004, for PCT patent application no. PCT/US03/13015, 4 pages.		
	199.	Abdallah, A. N. et al. (1997) "Evaluation of plasma levels of tumour necrosis factor alpha and interleukin-6 as rejection markers in a cohort of 142 heart-grafted patients followed by endomyocardial biopsy" <i>European Heart Journal</i> 18: 1024-1029.		
	200.	Ajjan, R. A. et al. (1996) "Intrathyroidal cytokine gene expression in Hashimoto's thyroiditis" <i>Clin. Exp. Immunol.</i> 105: 523-528.		
	201.	Akalin, Enver et al. (2001) "Gene Expression Analysis in Human Renal Allograft Biopsy Samples Using High-Density Oligoarray Technology" <i>Transplantation</i> 72 (5): 948-953.		
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	205.	Alpert, Susan et al. (1995) "The Relationship of Granzyme A and Perforin Expression to Cardiac Allograft Rejection and Dysfunction" <i>Transplantation</i> 60 (12): 1478-1485.		
	206.	Arnett, F. C. et al. (1988) "The American Rheumatism Association 1987 revised criteria for the classification of rheumatoid arthritis" <i>Arthritis Rheum</i> 31: 315-24.		

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